

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicants: Futoshi OKADA et al

For: ANTI-TUMOR AGENT

Serial No.: 10/655 567 Group: 1651

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Commissioner for Patents
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DECLARATION UNDER 37 CFR 1.132

I, the undersigned, hereby declare:

I am one of the co-inventors of the invention described and claimed in application Serial No. 10/655 567, filed on September 4, 2003.

I hereby incorporate by reference herein the contents of the Production Example and Example contained on pages 6-10 of the present specification.

I have performed an additional test to illustrate that the SOD combined with gliadin of the present invention is effective in increasing SOD levels throughout the body and not just at the administration site.

Mice were dietarily administered 2 IU of melon SOD/gliadin, melon extract containing 2 IU of SOD and gliadin twice a week for an eight week period and the tissue levels of SOD were obtained. The results are shown in the below Table.

Diet	Tissue			
	Liver*	Kidney*	Intestine*	Blood**
Control	1852±26	822±86	208±55	312±25
Melon extract	1825±42	870±58	235±12	308±12
Gliadin	1925±36	862±65	285±40	313±32
SOD/Gliadin	3575±42	2513±85	425±32	525±33

* Values are expressed as SOD units per gram of fresh tissues

** Values are expressed as SOD units per 5 x 10 cells

DISCUSSION OF RESULTS

As shown in the Table above, SOD/gliadin affected a significant increase in SOD levels throughout the body while SOD melon extract alone did not affect such an increase.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: _____

ANTI-TUMOR AGENT

ABSTRACT

The invention prevents or treats a tumor, inhibiting tumor growth and malignant progression by providing an antitumor agent ~~comprising~~containing a treated SOD as the active ingredient, especially a melon SOD coated with gliadin. The invention also applies to a method of preventing or treating the tumor.